

Version: Mar2010
Contract/Lab: All Laboratories
Species: RATS
Strain: F 344/N
Length of Study: CHRONIC

Toxicology Data Management System
Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: FEED

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Study Summary

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical
Male							
Southern Research Institute	059902703	08/12/02	729	50(3)	37(705)	452.8	Chromium picolinate monohydrate
Battelle Columbus Laboratory	050517405	08/05/02	729	50(3)	33(703)	510.0	Cresols
Southern Research Institute	059900705	04/21/03	729	50(3)	33(679)	460.9	Goldenseal root powder
Southern Research Institute	052000803	03/04/03	729	50(3)	36(704)	452.1	Milk thistle extract
Female							
Southern Research Institute	059902703	08/12/02	733	50(5)	36(702)	314.7	Chromium picolinate monohydrate
Battelle Columbus Laboratory	050517405	N/A	N/A	0(0)	0(0)	N/A	Cresols
Southern Research Institute	059900705	04/21/03	731	50(5)	30(699)	326.0	Goldenseal root powder
Southern Research Institute	052000803	03/04/03	732	50(5)	38(693)	328.4	Milk thistle extract

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Male					Female				
#All Organs: Benign Tumors									
		49/50 (98%)	50/50 (100%)	47/50 (94%)		45/50 (90%)		46/50 (92%)	
		50/50 (100%)				39/50 (78%)			
Overall Incidence	Total	196/200 (98%)	Mean 98%	SD 2.83%	Total	130/150 (86.67%)	Mean 86.67%	SD 7.57%	
#All Organs: Malignant Tumors									
		27/50 (54%)	23/50 (46%)	29/50 (58%)		15/50 (30%)		19/50 (38%)	
		26/50 (52%)				18/50 (36%)			
Overall Incidence	Total	105/200 (52.5%)	Mean 52.5%	SD 5%	Total	52/150 (34.67%)	Mean 34.67%	SD 4.16%	
#All Organs: Malignant and Benign Tumors									
		50/50 (100%)	50/50 (100%)	50/50 (100%)		47/50 (94%)		48/50 (96%)	
		50/50 (100%)				46/50 (92%)			
Overall Incidence	Total	200/200 (100%)	Mean 100%	SD 0%	Total	141/150 (94%)	Mean 94%	SD 2%	
#All Organs: Hemangioma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)		0/50 (0%)	
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/150 (0%)	Mean 0%	SD 0%	
#All Organs: Hemangiosarcoma									
		2/50 (4%)	0/50 (0%)	0/50 (0%)		0/50 (0%)		0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 2%	Total	0/150 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically
#: Denominator is number of animals necropsied

Male							Female				
#All Organs: Hemangiosarcoma or Hemangioma											
		2/50	(4%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		1/50	(2%)					0/50	(0%)		
Overall Incidence	Total	3/200	(1.5%)	Mean	1.5%	SD	1.91%	Total	0/150	(0%)	Mean 0% SD 0%
#All Organs: Histiocytic Sarcoma											
		0/50	(0%)	0/50	(0%)	0/50	(0%)	1/50	(2%)	1/50	(2%)
		3/50	(6%)					0/50	(0%)		
Overall Incidence	Total	3/200	(1.5%)	Mean	1.5%	SD	3%	Total	2/150	(1.33%)	Mean 1.33% SD 1.15%
#All Organs: Leukemia: Erythrocytic											
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)					1/50	(2%)		
Overall Incidence	Total	0/200	(0%)	Mean	0%	SD	0%	Total	1/150	(0.67%)	Mean 0.67% SD 1.15%
#All Organs: Leukemia: Lymphocytic, Monocytic, Mononuclear, or Undifferentiated											
		19/50	(38%)	15/50	(30%)	21/50	(42%)	9/50	(18%)	9/50	(18%)
		17/50	(34%)					6/50	(12%)		
Overall Incidence	Total	72/200	(36%)	Mean	36%	SD	5.16%	Total	24/150	(16%)	Mean 16% SD 3.46%
#All Organs: Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type											
		0/50	(0%)	1/50	(2%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)					0/50	(0%)		
Overall Incidence	Total	1/200	(0.5%)	Mean	0.5%	SD	1%	Total	0/150	(0%)	Mean 0% SD 0%

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Male												Female			
#All Organs:															
Mesothelioma: Benign															
		0/50	(0%)	0/50	(0%)	0/50	(0%)			0/50	(0%)			0/50	(0%)
		0/50	(0%)							0/50	(0%)				
Overall Incidence	Total	0/200	(0%)	Mean	0%	SD	0%		Total	0/150	(0%)	Mean	0%	SD	0%
#All Organs:															
Mesothelioma: Benign, Malignant, NOS															
		1/50	(2%)	0/50	(0%)	0/50	(0%)			0/50	(0%)			0/50	(0%)
		0/50	(0%)							0/50	(0%)				
Overall Incidence	Total	1/200	(0.5%)	Mean	0.5%	SD	1%		Total	0/150	(0%)	Mean	0%	SD	0%
#All Organs:															
Mesothelioma: Malignant															
		1/50	(2%)	0/50	(0%)	0/50	(0%)			0/50	(0%)			0/50	(0%)
		0/50	(0%)							0/50	(0%)				
Overall Incidence	Total	1/200	(0.5%)	Mean	0.5%	SD	1%		Total	0/150	(0%)	Mean	0%	SD	0%
#All Organs:															
Osteoma															
		0/50	(0%)	0/50	(0%)	0/50	(0%)			0/50	(0%)			0/50	(0%)
		1/50	(2%)							0/50	(0%)				
Overall Incidence	Total	1/200	(0.5%)	Mean	0.5%	SD	1%		Total	0/150	(0%)	Mean	0%	SD	0%
#All Organs:															
Osteosarcoma															
		0/50	(0%)	0/50	(0%)	2/50	(4%)			0/50	(0%)			0/50	(0%)
		0/50	(0%)							0/50	(0%)				
Overall Incidence	Total	2/200	(1%)	Mean	1%	SD	2%		Total	0/150	(0%)	Mean	0%	SD	0%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

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Male												Female			
#All Organs:															
Osteosarcoma or Osteoma															
		0/50	(0%)	0/50	(0%)	2/50	(4%)			0/50	(0%)			0/50	(0%)
		1/50	(2%)							0/50	(0%)				
Overall Incidence	Total	3/200	(1.5%)	Mean	1.5%	SD	1.91%	Total	0/150	(0%)	Mean	0%	SD	0%	
*Adrenal Cortex:															
Adenoma															
		0/50	(0%)	0/50	(0%)	0/50	(0%)			2/50	(4%)			1/50	(2%)
		2/50	(4%)							0/48	(0%)				
Overall Incidence	Total	2/200	(1%)	Mean	1%	SD	2%	Total	3/148	(2.03%)	Mean	2%	SD	2%	
*Adrenal Cortex:															
Carcinoma															
		0/50	(0%)	0/50	(0%)	0/50	(0%)			0/50	(0%)			0/50	(0%)
		0/50	(0%)							0/48	(0%)				
Overall Incidence	Total	0/200	(0%)	Mean	0%	SD	0%	Total	0/148	(0%)	Mean	0%	SD	0%	
*Adrenal Medulla:															
Ganglioneuroma															
		0/50	(0%)	0/50	(0%)	0/49	(0%)			0/50	(0%)			0/48	(0%)
		0/50	(0%)							0/48	(0%)				
Overall Incidence	Total	0/199	(0%)	Mean	0%	SD	0%	Total	0/146	(0%)	Mean	0%	SD	0%	
*Adrenal Medulla:															
Hemangioma															
		0/50	(0%)	0/50	(0%)	0/49	(0%)			0/50	(0%)			0/48	(0%)
		0/50	(0%)							0/48	(0%)				
Overall Incidence	Total	0/199	(0%)	Mean	0%	SD	0%	Total	0/146	(0%)	Mean	0%	SD	0%	

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Male					Female				
*Adrenal Medulla: Pheochromocytoma Benign									
		8/50 (16%) 5/50 (10%)	8/50 (16%)	5/49 (10%)		1/50 (2%) 1/48 (2%)		0/48 (0%)	
Overall Incidence	Total	26/199 (13.07%)	Mean 13.05%	SD 3.41%	Total	2/146 (1.37%)	Mean 1.36%	SD 1.18%	
.....									
*Adrenal Medulla: Pheochromocytoma Complex									
		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 1/48 (2%)		0/48 (0%)	
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	1/146 (0.68%)	Mean 0.69%	SD 1.2%	
.....									
*Adrenal Medulla: Pheochromocytoma Malignant									
		3/50 (6%) 0/50 (0%)	0/50 (0%)	1/49 (2%)		2/50 (4%) 0/48 (0%)		0/48 (0%)	
Overall Incidence	Total	4/199 (2.01%)	Mean 2.01%	SD 2.83%	Total	2/146 (1.37%)	Mean 1.33%	SD 2.31%	
.....									
*Adrenal Medulla: Pheochromocytoma: Benign, Complex, Malignant, NOS									
		11/50 (22%) 6/50 (12%)	8/50 (16%)	6/49 (12%)		3/50 (6%) 2/48 (4%)		0/48 (0%)	
Overall Incidence	Total	31/199 (15.58%)	Mean 15.56%	SD 4.67%	Total	5/146 (3.42%)	Mean 3.39%	SD 3.07%	
.....									
#Bone: Chondrosarcoma									
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)		0/50 (0%)	
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									

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Male					Female				
#Bone:									
Chondrosarcoma or Chondroma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)		0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
#Bone:									
Chordoma									
		0/50 (0%)	1/50 (2%)	1/50 (2%)		0/50 (0%)		0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
#Bone:									
Osteoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)		0/50 (0%)	
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
#Bone:									
Osteosarcoma									
		0/50 (0%)	0/50 (0%)	2/50 (4%)		0/50 (0%)		0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 2%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
#Bone:									
Osteosarcoma or Osteoma									
		0/50 (0%)	0/50 (0%)	2/50 (4%)		0/50 (0%)		0/50 (0%)	
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	3/200 (1.5%)	Mean 1.5%	SD 1.91%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									

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Length of Study: CHRONIC

Vehicle: FEED

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Male												Female			
*Brain: Astrocytoma Malignant															
		0/50	(0%)	0/50	(0%)	0/49	(0%)			0/50	(0%)			0/50	(0%)
		0/50	(0%)							0/50	(0%)				
Overall Incidence	Total	0/199 (0%)		Mean	0%	SD	0%	Total		0/150 (0%)		Mean	0%	SD	0%
.....															
*Brain: Ependymoma Benign															
		0/50	(0%)	0/50	(0%)	0/49	(0%)			0/50	(0%)			0/50	(0%)
		0/50	(0%)							0/50	(0%)				
Overall Incidence	Total	0/199 (0%)		Mean	0%	SD	0%	Total		0/150 (0%)		Mean	0%	SD	0%
.....															
*Brain: Ependymoma Malignant															
		0/50	(0%)	0/50	(0%)	1/49	(2%)			0/50	(0%)			0/50	(0%)
		0/50	(0%)							0/50	(0%)				
Overall Incidence	Total	1/199 (0.5%)		Mean	0.51%	SD	1.02%	Total		0/150 (0%)		Mean	0%	SD	0%
.....															
*Brain: Glioma Malignant															
		0/50	(0%)	0/50	(0%)	0/49	(0%)			0/50	(0%)			0/50	(0%)
		0/50	(0%)							0/50	(0%)				
Overall Incidence	Total	0/199 (0%)		Mean	0%	SD	0%	Total		0/150 (0%)		Mean	0%	SD	0%
.....															
*Brain: Granular Cell Tumor Benign															
		2/50	(4%)	0/50	(0%)	0/49	(0%)			0/50	(0%)			0/50	(0%)
		0/50	(0%)							0/50	(0%)				
Overall Incidence	Total	2/199 (1.01%)		Mean	1%	SD	2%	Total		0/150 (0%)		Mean	0%	SD	0%

#: Denominator is number of animals necropsied

Length of Study: CHRONIC

Vehicle: FEED

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Male										Female				
*Brain: Medulloblastoma Mal														
		0/50	(0%)	0/50	(0%)	0/49	(0%)			0/50	(0%)	0/50	(0%)	
		0/50	(0%)							0/50	(0%)			
Overall Incidence	Total	0/199	(0%)	Mean	0%	SD	0%	Total	0/150	(0%)	Mean	0%	SD	0%
*Brain: Oligodendroglioma Benign														
		0/50	(0%)	0/50	(0%)	0/49	(0%)			0/50	(0%)	0/50	(0%)	
		0/50	(0%)							0/50	(0%)			
Overall Incidence	Total	0/199	(0%)	Mean	0%	SD	0%	Total	0/150	(0%)	Mean	0%	SD	0%
*Brain: Oligodendroglioma Malignant														
		0/50	(0%)	0/50	(0%)	0/49	(0%)			0/50	(0%)	0/50	(0%)	
		0/50	(0%)							1/50	(2%)			
Overall Incidence	Total	0/199	(0%)	Mean	0%	SD	0%	Total	1/150	(0.67%)	Mean	0.67%	SD	1.15%
*Brain: Oligodendroglioma, Glioma, or Astrocytoma														
		0/50	(0%)	0/50	(0%)	0/49	(0%)			0/50	(0%)	0/50	(0%)	
		0/50	(0%)							1/50	(2%)			
Overall Incidence	Total	0/199	(0%)	Mean	0%	SD	0%	Total	1/150	(0.67%)	Mean	0.67%	SD	1.15%
*Brain: Osteosarcoma														
		0/50	(0%)	0/50	(0%)	0/49	(0%)			0/50	(0%)	0/50	(0%)	
		0/50	(0%)							0/50	(0%)			
Overall Incidence	Total	0/199	(0%)	Mean	0%	SD	0%	Total	0/150	(0%)	Mean	0%	SD	0%

#: Denominator is number of animals necropsied

		Male				Female			
*Brain:									
Schwannoma Malignant									
		0/50	(0%)	0/50	(0%)	0/49	(0%)	0/50	(0%)
		0/50	(0%)					0/50	(0%)
Overall Incidence	Total	0/199	(0%)	Mean 0%	SD 0%	Total	0/150	(0%)	Mean 0%
									SD 0%
*Clitoral/Preputial Gland:									
Adenoma									
		1/50	(2%)	5/50	(10%)	0/50	(0%)	10/50	(20%)
		1/50	(2%)					11/50	(22%)
Overall Incidence	Total	7/200	(3.5%)	Mean 3.5%	SD 4.43%	Total	26/150	(17.33%)	Mean 17.33%
									SD 6.43%
*Clitoral/Preputial Gland:									
Carcinoma									
		0/50	(0%)	0/50	(0%)	2/50	(4%)	0/50	(0%)
		2/50	(4%)					3/50	(6%)
Overall Incidence	Total	4/200	(2%)	Mean 2%	SD 2.31%	Total	7/150	(4.67%)	Mean 4.67%
									SD 4.16%
*Clitoral/Preputial Gland:									
Carcinoma or Adenoma									
		1/50	(2%)	5/50	(10%)	2/50	(4%)	10/50	(20%)
		3/50	(6%)					14/50	(28%)
Overall Incidence	Total	11/200	(5.5%)	Mean 5.5%	SD 3.42%	Total	33/150	(22%)	Mean 22%
									SD 5.29%
*Clitoral/Preputial Gland:									
Fibrosarcoma									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)					0/50	(0%)
Overall Incidence	Total	0/200	(0%)	Mean 0%	SD 0%	Total	0/150	(0%)	Mean 0%
									SD 0%

*: Denominator is number of animals with tissues examined microscopically
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Male												Female			
*Clitoral/Preputial Gland: Sarcoma															
		0/50	(0%)	0/50	(0%)	0/50	(0%)			0/50	(0%)			0/50	(0%)
		0/50	(0%)							0/50	(0%)				
Overall Incidence	Total	0/200	(0%)	Mean	0%	SD	0%		Total	0/150	(0%)	Mean	0%	SD	0%

#Ear: Neural Crest Tumor															
		0/50	(0%)	0/50	(0%)	0/50	(0%)			0/50	(0%)			0/50	(0%)
		0/50	(0%)							0/50	(0%)				
Overall Incidence	Total	0/200	(0%)	Mean	0%	SD	0%		Total	0/150	(0%)	Mean	0%	SD	0%

#Esophagus: Fibrosarcoma															
		0/50	(0%)	0/50	(0%)	0/50	(0%)			0/50	(0%)			0/50	(0%)
		0/50	(0%)							0/50	(0%)				
Overall Incidence	Total	0/200	(0%)	Mean	0%	SD	0%		Total	0/150	(0%)	Mean	0%	SD	0%

#Esophagus: Lipoma															
		0/50	(0%)	0/50	(0%)	0/50	(0%)			0/50	(0%)			0/50	(0%)
		0/50	(0%)							0/50	(0%)				
Overall Incidence	Total	0/200	(0%)	Mean	0%	SD	0%		Total	0/150	(0%)	Mean	0%	SD	0%

#Eye: Melanoma Malignant															
		0/50	(0%)	0/50	(0%)	0/50	(0%)			0/50	(0%)			0/50	(0%)
		0/50	(0%)							0/50	(0%)				
Overall Incidence	Total	0/200	(0%)	Mean	0%	SD	0%		Total	0/150	(0%)	Mean	0%	SD	0%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

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		Male						Female						
#Eye:														
Schwannoma Malignant														
		0/50	(0%)	1/50	(2%)	0/50	(0%)		0/50	(0%)	0/50	(0%)		
		0/50	(0%)						0/50	(0%)				
Overall Incidence	Total	1/200	(0.5%)	Mean	0.5%	SD	1%	Total	0/150	(0%)	Mean	0%	SD	0%
.....														
#Harderian Gland:														
Carcinoma														
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)		
		0/50	(0%)						0/50	(0%)				
Overall Incidence	Total	0/200	(0%)	Mean	0%	SD	0%	Total	0/150	(0%)	Mean	0%	SD	0%
.....														
#Harderian Gland:														
Carcinoma or Adenoma														
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)		
		0/50	(0%)						0/50	(0%)				
Overall Incidence	Total	0/200	(0%)	Mean	0%	SD	0%	Total	0/150	(0%)	Mean	0%	SD	0%
.....														
*Heart:														
Schwannoma Benign														
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)		
		0/50	(0%)						0/50	(0%)				
Overall Incidence	Total	0/200	(0%)	Mean	0%	SD	0%	Total	0/150	(0%)	Mean	0%	SD	0%
.....														
*Heart:														
Schwannoma Malignant														
		1/50	(2%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	1/50	(2%)		
		1/50	(2%)						0/50	(0%)				
Overall Incidence	Total	2/200	(1%)	Mean	1%	SD	1.15%	Total	1/150	(0.67%)	Mean	0.67%	SD	1.15%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Length of Study: CHRONIC

Vehicle: FEED

Report Date: 03/20/2010

Overall Incidence of Intestine Large: Colon/Rectum: Adenoma											
Male						Female					
		1/50 0/50	(2%) (0%)	0/50	(0%)	0/50	(0%)			0/50 0/50	(0%) (0%)
Overall Incidence	Total	1/200	(0.5%)	Mean	0.5%	SD	1%	Total	0/150	(0%)	Mean 0% SD 0%

Overall Incidence of Intestine Large: Colon/Rectum: Carcinoma											
		0/50 0/50	(0%) (0%)	0/50	(0%)	0/50	(0%)			0/50 0/50	(0%) (0%)
Overall Incidence	Total	0/200	(0%)	Mean	0%	SD	0%	Total	0/150	(0%)	Mean 0% SD 0%

Overall Incidence of Intestine Large: Colon/Rectum: Carcinoma or Adenoma											
		1/50 0/50	(2%) (0%)	0/50	(0%)	0/50	(0%)			0/50 0/50	(0%) (0%)
Overall Incidence	Total	1/200	(0.5%)	Mean	0.5%	SD	1%	Total	0/150	(0%)	Mean 0% SD 0%

Overall Incidence of Intestine Large: Colon/Rectum: Hemangioma											
		0/50 1/50	(0%) (2%)	0/50	(0%)	0/50	(0%)			0/50 0/50	(0%) (0%)
Overall Incidence	Total	1/200	(0.5%)	Mean	0.5%	SD	1%	Total	0/150	(0%)	Mean 0% SD 0%

Overall Incidence of Intestine Small: Duodenum: Carcinoma											
		1/50 0/50	(2%) (0%)	0/50	(0%)	0/50	(0%)			0/50 0/50	(0%) (0%)
Overall Incidence	Total	1/200	(0.5%)	Mean	0.5%	SD	1%	Total	0/150	(0%)	Mean 0% SD 0%

#: Denominator is number of animals necropsied

Version: Mar2010

Contract/Lab: All Laboratories

Species: RATS

Strain: F 344/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL

Vehicle: FEED

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Report Date: 03/20/2010

Male												Female			
#Intestine Small: Duodenum: Leiomyoma															
		0/50	(0%)	0/50	(0%)	0/50	(0%)			0/50	(0%)			0/50	(0%)
		0/50	(0%)							0/50	(0%)				
Overall Incidence	Total	0/200	(0%)	Mean	0%	SD	0%		Total	0/150	(0%)	Mean	0%	SD	0%
#Intestine Small: Ileum: Adenoma															
		0/50	(0%)	0/50	(0%)	0/50	(0%)			0/50	(0%)			0/50	(0%)
		0/50	(0%)							0/50	(0%)				
Overall Incidence	Total	0/200	(0%)	Mean	0%	SD	0%		Total	0/150	(0%)	Mean	0%	SD	0%
#Intestine Small: Jejunum: Carcinoma															
		0/50	(0%)	0/50	(0%)	0/50	(0%)			0/50	(0%)			0/50	(0%)
		0/50	(0%)							0/50	(0%)				
Overall Incidence	Total	0/200	(0%)	Mean	0%	SD	0%		Total	0/150	(0%)	Mean	0%	SD	0%
#Intestine Small: Jejunum: Granular Cell Tumor Malignant															
		0/50	(0%)	0/50	(0%)	0/50	(0%)			0/50	(0%)			0/50	(0%)
		0/50	(0%)							0/50	(0%)				
Overall Incidence	Total	0/200	(0%)	Mean	0%	SD	0%		Total	0/150	(0%)	Mean	0%	SD	0%
#Intestine Small: Jejunum: Leiomyoma															
		0/50	(0%)	0/50	(0%)	0/50	(0%)			0/50	(0%)			0/50	(0%)
		0/50	(0%)							0/50	(0%)				
Overall Incidence	Total	0/200	(0%)	Mean	0%	SD	0%		Total	0/150	(0%)	Mean	0%	SD	0%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010

Contract/Lab: All Laboratories

Species: RATS

Strain: F 344/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL

Vehicle: FEED

Page: 202

Report Date: 03/20/2010

Male										Female					
#Intestine Small: Jejunum: Leiomyosarcoma															
		0/50	(0%)	0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)		
		0/50	(0%)							0/50	(0%)				
Overall Incidence	Total	0/200	(0%)	Mean	0%	SD	0%	Total		0/150	(0%)	Mean	0%	SD	0%

#Intestine Small: Site Unspecified: Adenoma															
		0/50	(0%)	0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)		
		0/50	(0%)							0/50	(0%)				
Overall Incidence	Total	0/200	(0%)	Mean	0%	SD	0%	Total		0/150	(0%)	Mean	0%	SD	0%

#Intestine Small: Site Unspecified: Carcinoma															
		1/50	(2%)	0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)		
		0/50	(0%)							0/50	(0%)				
Overall Incidence	Total	1/200	(0.5%)	Mean	0.5%	SD	1%	Total		0/150	(0%)	Mean	0%	SD	0%

#Intestine Small: Site Unspecified: Carcinoma or Adenoma															
		1/50	(2%)	0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)		
		0/50	(0%)							0/50	(0%)				
Overall Incidence	Total	1/200	(0.5%)	Mean	0.5%	SD	1%	Total		0/150	(0%)	Mean	0%	SD	0%

#Intestine Small: Site Unspecified: Granular Cell Tumor Malignant															
		0/50	(0%)	0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)		
		0/50	(0%)							0/50	(0%)				
Overall Incidence	Total	0/200	(0%)	Mean	0%	SD	0%	Total		0/150	(0%)	Mean	0%	SD	0%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Male						Female					
#Intestine Small: Site Unspecified: Leiomyoma											
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	
		0/50	(0%)					0/50	(0%)		
Overall Incidence	Total	0/200	(0%)	Mean 0%	SD 0%			Total	0/150	(0%)	Mean 0% SD 0%
#Intestine Small: Site Unspecified: Leiomyosarcoma											
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	
		0/50	(0%)					0/50	(0%)		
Overall Incidence	Total	0/200	(0%)	Mean 0%	SD 0%			Total	0/150	(0%)	Mean 0% SD 0%
*Islets, Pancreatic: Adenoma											
		1/50	(2%)	1/49	(2%)	7/50	(14%)		2/49	(4%)	0/49 (0%)
		3/50	(6%)						0/48	(0%)	
Overall Incidence	Total	12/199	(6.03%)	Mean 6.01%	SD 5.65%			Total	2/146	(1.37%)	Mean 1.36% SD 2.36%
*Islets, Pancreatic: Carcinoma											
		1/50	(2%)	1/49	(2%)	0/50	(0%)		0/49	(0%)	0/49 (0%)
		1/50	(2%)						0/48	(0%)	
Overall Incidence	Total	3/199	(1.51%)	Mean 1.51%	SD 1.01%			Total	0/146	(0%)	Mean 0% SD 0%
*Islets, Pancreatic: Carcinoma or Adenoma											
		2/50	(4%)	2/49	(4%)	7/50	(14%)		2/49	(4%)	0/49 (0%)
		4/50	(8%)						0/48	(0%)	
Overall Incidence	Total	15/199	(7.54%)	Mean 7.52%	SD 4.71%			Total	2/146	(1.37%)	Mean 1.36% SD 2.36%

#: Denominator is number of animals with tissues examined microscopically
#: Denominator is number of animals necropsied

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Vehicle: FEED

Report Date: 03/20/2010

		Male						Female						
*Kidney: Pelvis and Transitional Epithelium: Carcinoma														
		0/50 0/50	(0%) (0%)	0/50	(0%)	1/50	(2%)			0/47 0/48	(0%) (0%)	0/49	(0%)	
Overall Incidence	Total	1/200	(0.5%)	Mean	0.5%	SD	1%	Total	0/144	(0%)	Mean	0%	SD	0%
<hr/>														
*Kidney: Pelvis and Transitional Epithelium: Carcinoma or Adenoma														
		0/50 0/50	(0%) (0%)	0/50	(0%)	1/50	(2%)			0/47 0/48	(0%) (0%)	0/49	(0%)	
Overall Incidence	Total	1/200	(0.5%)	Mean	0.5%	SD	1%	Total	0/144	(0%)	Mean	0%	SD	0%
<hr/>														
*Kidney: Pelvis and Transitional Epithelium: Papilloma														
		0/50 0/50	(0%) (0%)	0/50	(0%)	0/50	(0%)			0/47 0/48	(0%) (0%)	0/49	(0%)	
Overall Incidence	Total	0/200	(0%)	Mean	0%	SD	0%	Total	0/144	(0%)	Mean	0%	SD	0%
<hr/>														
*Kidney: Renal Tubule: Adenoma														
		0/50 0/50	(0%) (0%)	0/50	(0%)	0/50	(0%)			0/47 0/48	(0%) (0%)	0/49	(0%)	
Overall Incidence	Total	0/200	(0%)	Mean	0%	SD	0%	Total	0/144	(0%)	Mean	0%	SD	0%
<hr/>														
*Kidney: Renal Tubule: Carcinoma														
		0/50 0/50	(0%) (0%)	0/50	(0%)	0/50	(0%)			0/47 0/48	(0%) (0%)	0/49	(0%)	
Overall Incidence	Total	0/200	(0%)	Mean	0%	SD	0%	Total	0/144	(0%)	Mean	0%	SD	0%

#: Denominator is number of animals necropsied

Version: Mar2010

Contract/Lab: All Laboratories

Species: RATS

Strain: F 344/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL

Vehicle: FEED

Page: 205

Report Date: 03/20/2010

Male										Female					
*Kidney: Renal Tubule: Carcinoma or Adenoma															
		0/50	(0%)	0/50	(0%)	0/50	(0%)			0/47	(0%)			0/49	(0%)
		0/50	(0%)							0/48	(0%)				
Overall Incidence	Total	0/200	(0%)	Mean	0%	SD	0%	Total	0/144	(0%)	Mean	0%	SD	0%	
.....															
*Kidney: Renal Tubule: Hemangiosarcoma															
		0/50	(0%)	0/50	(0%)	0/50	(0%)			0/47	(0%)			0/49	(0%)
		0/50	(0%)							0/48	(0%)				
Overall Incidence	Total	0/200	(0%)	Mean	0%	SD	0%	Total	0/144	(0%)	Mean	0%	SD	0%	
.....															
*Kidney: Renal Tubule: Lipoma															
		0/50	(0%)	0/50	(0%)	0/50	(0%)			0/47	(0%)			0/49	(0%)
		0/50	(0%)							0/48	(0%)				
Overall Incidence	Total	0/200	(0%)	Mean	0%	SD	0%	Total	0/144	(0%)	Mean	0%	SD	0%	
.....															
*Kidney: Renal Tubule: Mesenchymal Tumor Benign															
		0/50	(0%)	0/50	(0%)	0/50	(0%)			0/47	(0%)			0/49	(0%)
		0/50	(0%)							0/48	(0%)				
Overall Incidence	Total	0/200	(0%)	Mean	0%	SD	0%	Total	0/144	(0%)	Mean	0%	SD	0%	
.....															
*Kidney: Renal Tubule: Mesenchymal Tumor Malignant															
		0/50	(0%)	0/50	(0%)	0/50	(0%)			0/47	(0%)			0/49	(0%)
		0/50	(0%)							0/48	(0%)				
Overall Incidence	Total	0/200	(0%)	Mean	0%	SD	0%	Total	0/144	(0%)	Mean	0%	SD	0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

		Male						Female						
*Kidney: Renal Tubule: Nephroblastoma														
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/47	(0%)		0/49	(0%)	
		0/50	(0%)						0/48	(0%)				
Overall Incidence	Total	0/200	(0%)	Mean	0%	SD	0%	Total	0/144	(0%)	Mean	0%	SD	0%
*Kidney: Renal Tubule: Sarcoma														
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/47	(0%)		1/49	(2%)	
		0/50	(0%)						0/48	(0%)				
Overall Incidence	Total	0/200	(0%)	Mean	0%	SD	0%	Total	1/144	(0.69%)	Mean	0.68%	SD	1.18%
*Liver: Cholangioma														
		1/50	(2%)	0/50	(0%)	0/50	(0%)		0/50	(0%)		0/50	(0%)	
		1/50	(2%)						0/50	(0%)				
Overall Incidence	Total	2/200	(1%)	Mean	1%	SD	1.15%	Total	0/150	(0%)	Mean	0%	SD	0%
*Liver: Hemangiosarcoma														
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)		0/50	(0%)	
		0/50	(0%)						0/50	(0%)				
Overall Incidence	Total	0/200	(0%)	Mean	0%	SD	0%	Total	0/150	(0%)	Mean	0%	SD	0%
*Liver: Hepatocellular Adenoma														
		1/50	(2%)	0/50	(0%)	1/50	(2%)		2/50	(4%)		0/50	(0%)	
		3/50	(6%)						2/50	(4%)				
Overall Incidence	Total	5/200	(2.5%)	Mean	2.5%	SD	2.52%	Total	4/150	(2.67%)	Mean	2.67%	SD	2.31%

*: Denominator is number of animals with tissues examined microscopically
#: Denominator is number of animals necropsied

Male						Female					
*Liver: Hepatocellular Carcinoma											
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)			0/50	(0%)	0/50	(0%)		
Overall Incidence	Total	0/200	(0%)	Mean 0%	SD 0%	Total	0/150	(0%)	Mean 0%	SD 0%	
*Liver: Hepatocellular Carcinoma or Hepatoblastoma											
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)			0/50	(0%)	0/50	(0%)		
Overall Incidence	Total	0/200	(0%)	Mean 0%	SD 0%	Total	0/150	(0%)	Mean 0%	SD 0%	
*Liver: Hepatocellular Carcinoma or Hepatocellular Adenoma											
		1/50	(2%)	0/50	(0%)	1/50	(2%)	2/50	(4%)	0/50	(0%)
		3/50	(6%)					2/50	(4%)		
Overall Incidence	Total	5/200	(2.5%)	Mean 2.5%	SD 2.52%	Total	4/150	(2.67%)	Mean 2.67%	SD 2.31%	
*Liver: Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma											
		1/50	(2%)	0/50	(0%)	1/50	(2%)	2/50	(4%)	0/50	(0%)
		3/50	(6%)					2/50	(4%)		
Overall Incidence	Total	5/200	(2.5%)	Mean 2.5%	SD 2.52%	Total	4/150	(2.67%)	Mean 2.67%	SD 2.31%	
*Liver: Ito Cell Tumor Benign											
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)					0/50	(0%)		
Overall Incidence	Total	0/200	(0%)	Mean 0%	SD 0%	Total	0/150	(0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically
#: Denominator is number of animals necropsied

Version: Mar2010

Contract/Lab: All Laboratories

Species: RATS

Strain: F 344/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL

Vehicle: FEED

Page: 208

Report Date: 03/20/2010

Male										Female				
*Lung: Alveolar/Bronchiolar Adenoma														
		0/50 1/50	(0%) (2%)	1/50	(2%)	0/50	(0%)			1/50	(2%)	0/50	(0%)	
Overall Incidence	Total	2/200 (1%)		Mean	1%	SD	1.15%	Total	2/150 (1.33%)		Mean	1.33%	SD	1.15%
*Lung: Alveolar/Bronchiolar Carcinoma														
		0/50 0/50	(0%) (0%)	0/50	(0%)	1/50	(2%)			0/50	(0%) 1/50 (2%)	0/50	(0%)	
Overall Incidence	Total	1/200 (0.5%)		Mean	0.5%	SD	1%	Total	1/150 (0.67%)		Mean	0.67%	SD	1.15%
*Lung: Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma														
		0/50 1/50	(0%) (2%)	1/50	(2%)	1/50	(2%)			1/50	(2%) 1/50 (2%)	1/50	(2%)	
Overall Incidence	Total	3/200 (1.5%)		Mean	1.5%	SD	1%	Total	3/150 (2%)		Mean	2%	SD	0%
*Lung: Fibrosarcoma														
		0/50 0/50	(0%) (0%)	0/50	(0%)	0/50	(0%)			0/50	(0%) 0/50 (0%)	0/50	(0%)	
Overall Incidence	Total	0/200 (0%)		Mean	0%	SD	0%	Total	0/150 (0%)		Mean	0%	SD	0%
*Lung: Hemangiosarcoma														
		0/50 0/50	(0%) (0%)	0/50	(0%)	0/50	(0%)			0/50	(0%) 0/50 (0%)	0/50	(0%)	
Overall Incidence	Total	0/200 (0%)		Mean	0%	SD	0%	Total	0/150 (0%)		Mean	0%	SD	0%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
Contract/Lab: All Laboratories
Species: RATS
Strain: F 344/N
Length of Study: CHRONIC

Toxicology Data Management System
Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: FEED

Page: 209
Report Date: 03/20/2010

Male						Female								
*Lung: Squamous Cell Carcinoma														
		1/50	(2%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)		
		0/50	(0%)						0/50	(0%)				
Overall Incidence	Total	1/200	(0.5%)	Mean	0.5%	SD	1%	Total	0/150	(0%)	Mean	0%	SD	0%
.....														
#Lymph Node: Hemangiosarcoma														
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)		
		0/50	(0%)						0/50	(0%)				
Overall Incidence	Total	0/200	(0%)	Mean	0%	SD	0%	Total	0/150	(0%)	Mean	0%	SD	0%
.....														
#Mammary Gland: Adenolipoma														
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)		
		0/50	(0%)						0/50	(0%)				
Overall Incidence	Total	0/200	(0%)	Mean	0%	SD	0%	Total	0/150	(0%)	Mean	0%	SD	0%
.....														
#Mammary Gland: Adenoma														
		0/50	(0%)	1/50	(2%)	0/50	(0%)		1/50	(2%)	2/50	(4%)		
		0/50	(0%)						0/50	(0%)				
Overall Incidence	Total	1/200	(0.5%)	Mean	0.5%	SD	1%	Total	3/150	(2%)	Mean	2%	SD	2%
.....														
#Mammary Gland: Carcinoma														
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	4/50	(8%)		
		0/50	(0%)						4/50	(8%)				
Overall Incidence	Total	0/200	(0%)	Mean	0%	SD	0%	Total	8/150	(5.33%)	Mean	5.33%	SD	4.62%
.....														

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Male										Female											
#Mammary Gland: Carcinoma or Adenoma																					
		0/50 (0%)		1/50 (2%)		0/50 (0%)				1/50 (2%)				6/50 (12%)							
		0/50 (0%)								4/50 (8%)											
Overall Incidence	Total	1/200 (0.5%)		Mean 0.5%		SD 1%				Total	11/150 (7.33%)		Mean 7.33%		SD 5.03%						
#Mammary Gland: Fibroadenoma																					
		2/50 (4%)		0/50 (0%)		1/50 (2%)				29/50 (58%)				30/50 (60%)							
		0/50 (0%)								28/50 (56%)											
Overall Incidence	Total	3/200 (1.5%)		Mean 1.5%		SD 1.91%				Total	87/150 (58%)		Mean 58%		SD 2%						
#Mammary Gland: Fibroma																					
		0/50 (0%)		0/50 (0%)		0/50 (0%)				0/50 (0%)				0/50 (0%)							
		0/50 (0%)								0/50 (0%)											
Overall Incidence	Total	0/200 (0%)		Mean 0%		SD 0%				Total	0/150 (0%)		Mean 0%		SD 0%						
#Mammary Gland: Fibroma, Fibroadenoma or Adenoma																					
		2/50 (4%)		1/50 (2%)		1/50 (2%)				30/50 (60%)				30/50 (60%)							
		0/50 (0%)								28/50 (56%)											
Overall Incidence	Total	4/200 (2%)		Mean 2%		SD 1.63%				Total	88/150 (58.67%)		Mean 58.67%		SD 2.31%						
#Mammary Gland: Fibroma, Fibroadenoma, Carcinoma, or Adenoma																					
		2/50 (4%)		1/50 (2%)		1/50 (2%)				30/50 (60%)				31/50 (62%)							
		0/50 (0%)								28/50 (56%)											
Overall Incidence	Total	4/200 (2%)		Mean 2%		SD 1.63%				Total	89/150 (59.33%)		Mean 59.33%		SD 3.06%						

*: Denominator is number of animals with tissues examined microscopically
#: Denominator is number of animals necropsied

		Male				Female					
#Mesentery: Fibrous Histiocytoma											
		0/50 0/50	(0%) (0%)	0/50	(0%)	0/50	(0%)	0/50 0/50	(0%) (0%)	0/50	(0%)
Overall Incidence	Total	0/200	(0%)	Mean	0%	SD	0%	Total	0/150	(0%)	Mean 0% SD 0%
#Mesentery: Hemangiosarcoma											
		1/50 0/50	(2%) (0%)	0/50	(0%)	0/50	(0%)	0/50 0/50	(0%) (0%)	0/50	(0%)
Overall Incidence	Total	1/200	(0.5%)	Mean	0.5%	SD	1%	Total	0/150	(0%)	Mean 0% SD 0%
#Mesentery: Lipoma											
		0/50 0/50	(0%) (0%)	0/50	(0%)	1/50	(2%)	0/50 0/50	(0%) (0%)	0/50	(0%)
Overall Incidence	Total	1/200	(0.5%)	Mean	0.5%	SD	1%	Total	0/150	(0%)	Mean 0% SD 0%
#Mesentery: Schwannoma Malignant											
		0/50 0/50	(0%) (0%)	0/50	(0%)	0/50	(0%)	0/50 0/50	(0%) (0%)	0/50	(0%)
Overall Incidence	Total	0/200	(0%)	Mean	0%	SD	0%	Total	0/150	(0%)	Mean 0% SD 0%
*Nose: Adenoma											
		0/50 0/50	(0%) (0%)	0/50	(0%)	0/50	(0%)	0/50 0/50	(0%) (0%)	0/50	(0%)
Overall Incidence	Total	0/200	(0%)	Mean	0%	SD	0%	Total	0/150	(0%)	Mean 0% SD 0%

*: Denominator is number of animals with tissues examined microscopically
#: Denominator is number of animals necropsied

		Male				Female			
*Nose: Chondroma									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)			0/50	(0%)		
Overall Incidence	Total	0/200	(0%)	Mean	0%	SD	0%	Total	0/150 (0%)
								Mean	0%
								SD	0%
*Nose: Squamous Cell Carcinoma									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)			0/50	(0%)		
Overall Incidence	Total	0/200	(0%)	Mean	0%	SD	0%	Total	0/150 (0%)
								Mean	0%
								SD	0%
#Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): Papilloma Squamous or Papilloma									
		1/50	(2%)	0/50	(0%)	1/50	(2%)	0/50	(0%)
		1/50	(2%)			0/50	(0%)		1/50 (2%)
Overall Incidence	Total	3/200	(1.5%)	Mean	1.5%	SD	1%	Total	1/150 (0.67%)
								Mean	0.67%
								SD	1.15%
#Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): Squamous Cell Carcinoma									
		0/50	(0%)	0/50	(0%)	1/50	(2%)	0/50	(0%)
		0/50	(0%)			0/50	(0%)		0/50 (0%)
Overall Incidence	Total	1/200	(0.5%)	Mean	0.5%	SD	1%	Total	0/150 (0%)
								Mean	0%
								SD	0%
#Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): Squamous Cell Carcinoma, Papilloma Squamous, or Papilloma									
		1/50	(2%)	0/50	(0%)	2/50	(4%)	0/50	(0%)
		1/50	(2%)			0/50	(0%)		1/50 (2%)
Overall Incidence	Total	4/200	(2%)	Mean	2%	SD	1.63%	Total	1/150 (0.67%)
								Mean	0.67%
								SD	1.15%

*: Denominator is number of animals with tissues examined microscopically
#: Denominator is number of animals necropsied

Length of Study: CHRONIC

Vehicle: FEED

Report Date: 03/20/2010

Overall Incidence of Ovarian Cancer											
		Male						Female			
#Oral Mucosa: Squamous Cell Carcinoma											
		0/50 0/50	(0%) (0%)	0/50	(0%)	1/50	(2%)	0/50 0/50	(0%) (0%)	0/50	(0%)
Overall Incidence	Total	1/200	(0.5%)	Mean	0.5%	SD	1%	Total	0/150	(0%)	Mean 0% SD 0%
#Oral Mucosa: Squamous Cell Papilloma											
		0/50 0/50	(0%) (0%)	0/50	(0%)	0/50	(0%)	0/50 0/50	(0%) (0%)	0/50	(0%)
Overall Incidence	Total	0/200	(0%)	Mean	0%	SD	0%	Total	0/150	(0%)	Mean 0% SD 0%
*Ovary: Cystadenoma											
								0/50 0/50	(0%) (0%)	0/50	(0%)
Overall Incidence								Total	0/150	(0%)	Mean 0% SD 0%
*Ovary: Granulosa Cell Tumor Benign											
								0/50 0/50	(0%) (0%)	0/50	(0%)
Overall Incidence								Total	0/150	(0%)	Mean 0% SD 0%
*Ovary: Granulosa Cell Tumor Malignant											
								0/50 2/50	(0%) (4%)	0/50	(0%)
Overall Incidence								Total	2/150	(1.33%)	Mean 1.33% SD 2.31%

#: Denominator is number of animals necropsied

Male					Female					
*Ovary:										
Granulosa Cell Tumor: Benign, Malignant, NOS										
					0/50	(0%)			0/50	(0%)
					2/50	(4%)				
Overall Incidence					Total	2/150 (1.33%)		Mean	1.33%	
								SD	2.31%	
*Ovary:										
Granulosa-Theca Tumor Benign										
					1/50	(2%)			0/50	(0%)
					0/50	(0%)				
Overall Incidence					Total	1/150 (0.67%)		Mean	0.67%	
								SD	1.15%	
*Ovary:										
Granulosa-Theca Tumor Malignant										
					0/50	(0%)			0/50	(0%)
					0/50	(0%)				
Overall Incidence					Total	0/150 (0%)		Mean	0%	
								SD	0%	
*Ovary:										
Tubulostromal Adenoma										
					0/50	(0%)			0/50	(0%)
					0/50	(0%)				
Overall Incidence					Total	0/150 (0%)		Mean	0%	
								SD	0%	
*Pancreas:										
Adenoma										
					0/49	(0%)			0/49	(0%)
					2/50	(4%)			0/50	(0%)
Overall Incidence					Total	2/198 (1.01%)		Mean	1%	
								SD	2%	
*: Denominator is number of animals with tissues examined microscopically										
#: Denominator is number of animals necropsied										

		Male				Female							
*Pancreas: Carcinoma													
		0/49 0/50	(0%) (0%)	0/49	(0%)	0/50	(0%)	0/49 0/48	(0%) (0%)	0/49	(0%)		
Overall Incidence	Total	0/198 (0%)		Mean	0%	SD	0%	Total	0/146 (0%)	Mean	0%	SD	0%
.....													
*Pancreas: Carcinoma or Adenoma													
		0/49 2/50	(0%) (4%)	0/49	(0%)	0/50	(0%)	0/49 0/48	(0%) (0%)	0/49	(0%)		
Overall Incidence	Total	2/198 (1.01%)		Mean	1%	SD	2%	Total	0/146 (0%)	Mean	0%	SD	0%
.....													
*Pancreas: Mixed Tumor Benign													
		0/49 0/50	(0%) (0%)	0/49	(0%)	0/50	(0%)	0/49 0/48	(0%) (0%)	0/49	(0%)		
Overall Incidence	Total	0/198 (0%)		Mean	0%	SD	0%	Total	0/146 (0%)	Mean	0%	SD	0%
.....													
*Pancreas: Mixed Tumor Malignant													
		0/49 0/50	(0%) (0%)	0/49	(0%)	1/50	(2%)	0/49 0/48	(0%) (0%)	0/49	(0%)		
Overall Incidence	Total	1/198 (0.51%)		Mean	0.5%	SD	1%	Total	0/146 (0%)	Mean	0%	SD	0%
.....													
*Parathyroid Gland: Adenoma													
		1/45 0/50	(2%) (0%)	1/46	(2%)	0/49	(0%)	0/48 0/49	(0%) (0%)	0/49	(0%)		
Overall Incidence	Total	2/190 (1.05%)		Mean	1.1%	SD	1.27%	Total	0/146 (0%)	Mean	0%	SD	0%
.....													

*: Denominator is number of animals with tissues examined microscopically
#: Denominator is number of animals necropsied

Male					Female				
*Pituitary Gland: Pars Distalis or Unspecified Site: Adenoma									
		10/50 (20%)	20/50 (40%)	8/50 (16%)		24/49 (49%)	25/50 (50%)		
		13/50 (26%)				20/50 (40%)			
Overall Incidence	Total	51/200 (25.5%)	Mean 25.5%	SD 10.5%	Total	69/149 (46.31%)	Mean 46.33%	SD 5.5%	
*Pituitary Gland: Pars Distalis or Unspecified Site: Carcinoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/49 (2%)	0/50 (0%)		
		0/50 (0%)				1/50 (2%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	2/149 (1.34%)	Mean 1.35%	SD 1.17%	
*Pituitary Gland: Pars Distalis or Unspecified Site: Carcinoma or Adenoma									
		10/50 (20%)	20/50 (40%)	8/50 (16%)		25/49 (51%)	25/50 (50%)		
		13/50 (26%)				21/50 (42%)			
Overall Incidence	Total	51/200 (25.5%)	Mean 25.5%	SD 10.5%	Total	71/149 (47.65%)	Mean 47.67%	SD 4.94%	
*Pituitary Gland: Pars Distalis or Unspecified Site: Ganglioneuroma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)		
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/149 (0%)	Mean 0%	SD 0%	
*Pituitary Gland: Pars Intermedia: Adenoma									
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/49 (0%)	0/50 (0%)		
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/149 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically
#: Denominator is number of animals necropsied

Version: Mar2010
Contract/Lab: All Laboratories
Species: RATS
Strain: F 344/N
Length of Study: CHRONIC

Toxicology Data Management System
Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: FEED

Male						Female					
*Pituitary Gland: Pars Intermedia: Carcinoma or Adenoma											
		0/50	(0%)	1/50	(2%)	0/50	(0%)			0/49	(0%)
		0/50	(0%)							0/50	(0%)
Overall Incidence	Total	1/200	(0.5%)	Mean	0.5%	SD	1%	Total	0/149	(0%)	Mean 0%
											SD 0%
.....											
*Pituitary Gland: Pars Nervosa: Craniopharyngioma											
		0/50	(0%)	0/50	(0%)	0/50	(0%)			0/49	(0%)
		0/50	(0%)							0/50	(0%)
Overall Incidence	Total	0/200	(0%)	Mean	0%	SD	0%	Total	0/149	(0%)	Mean 0%
											SD 0%
.....											
*Prostate: Adenoma											
		0/50	(0%)	0/50	(0%)	1/50	(2%)				
		0/50	(0%)								
Overall Incidence	Total	1/200	(0.5%)	Mean	0.5%	SD	1%				
.....											
*Prostate: Carcinoma or Adenoma											
		0/50	(0%)	0/50	(0%)	1/50	(2%)				
		0/50	(0%)								
Overall Incidence	Total	1/200	(0.5%)	Mean	0.5%	SD	1%				
.....											
*Salivary Glands: Carcinoma											
		0/50	(0%)	0/49	(0%)	0/50	(0%)			0/50	(0%)
		0/48	(0%)							0/50	(0%)
Overall Incidence	Total	0/197	(0%)	Mean	0%	SD	0%	Total	0/150	(0%)	Mean 0%
											SD 0%
.....											

*: Denominator is number of animals with tissues examined microscopically
#: Denominator is number of animals necropsied

		Male				Female					
*Salivary Glands: Carcinoma or Adenoma											
		0/50 0/48	(0%) (0%)	0/49	(0%)	0/50	(0%)	0/50 0/50	(0%) (0%)	0/50	(0%)
Overall Incidence	Total	0/197	(0%)	Mean	0%	SD	0%	Total	0/150	(0%)	Mean 0% SD 0%
*Salivary Glands: Sarcoma											
		0/50 0/48	(0%) (0%)	0/49	(0%)	0/50	(0%)	0/50 0/50	(0%) (0%)	0/50	(0%)
Overall Incidence	Total	0/197	(0%)	Mean	0%	SD	0%	Total	0/150	(0%)	Mean 0% SD 0%
*Salivary Glands: Schwannoma Malignant											
		0/50 0/48	(0%) (0%)	0/49	(0%)	0/50	(0%)	0/50 0/50	(0%) (0%)	0/50	(0%)
Overall Incidence	Total	0/197	(0%)	Mean	0%	SD	0%	Total	0/150	(0%)	Mean 0% SD 0%
#Seminal Vesicle: Adenoma											
		0/50 0/50	(0%) (0%)	0/50	(0%)	0/50	(0%)				
Overall Incidence	Total	0/200	(0%)	Mean	0%	SD	0%				
#Skeletal Muscle: Fibrous Histiocytoma											
		0/50 0/50	(0%) (0%)	0/50	(0%)	0/50	(0%)	0/50 0/50	(0%) (0%)	0/50	(0%)
Overall Incidence	Total	0/200	(0%)	Mean	0%	SD	0%	Total	0/150	(0%)	Mean 0% SD 0%

*: Denominator is number of animals with tissues examined microscopically
#: Denominator is number of animals necropsied

Version: Mar2010
Contract/Lab: All Laboratories
Species: RATS
Strain: F 344/N
Length of Study: CHRONIC

Toxicology Data Management System
Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: FEED

Male						Female								
#Skeletal Muscle: Hemangiosarcoma														
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)		
		0/50	(0%)					0/50	(0%)					
Overall Incidence	Total	0/200	(0%)	Mean	0%	SD	0%	Total	0/150	(0%)	Mean	0%	SD	0%
#Skeletal Muscle: Rhabdomyosarcoma														
		0/50	(0%)	0/50	(0%)	1/50	(2%)		0/50	(0%)	0/50	(0%)		
		0/50	(0%)					0/50	(0%)					
Overall Incidence	Total	1/200	(0.5%)	Mean	0.5%	SD	1%	Total	0/150	(0%)	Mean	0%	SD	0%
#Skeletal Muscle: Rhabdomyosarcoma or Rhabdomyoma														
		0/50	(0%)	0/50	(0%)	1/50	(2%)		0/50	(0%)	0/50	(0%)		
		0/50	(0%)					0/50	(0%)					
Overall Incidence	Total	1/200	(0.5%)	Mean	0.5%	SD	1%	Total	0/150	(0%)	Mean	0%	SD	0%
#Skin: Basal Cell Adenoma														
		1/50	(2%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)		
		0/50	(0%)					0/50	(0%)					
Overall Incidence	Total	1/200	(0.5%)	Mean	0.5%	SD	1%	Total	0/150	(0%)	Mean	0%	SD	0%
#Skin: Basal Cell Adenoma or Basosquamous Tumor Benign														
		1/50	(2%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)		
		0/50	(0%)					0/50	(0%)					
Overall Incidence	Total	1/200	(0.5%)	Mean	0.5%	SD	1%	Total	0/150	(0%)	Mean	0%	SD	0%

*: Denominator is number of animals with tissues examined microscopically
#: Denominator is number of animals necropsied

Version: Mar2010
Contract/Lab: All Laboratories
Species: RATS
Strain: F 344/N
Length of Study: CHRONIC

Toxicology Data Management System
Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: FEED

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Report Date: 03/20/2010

Male					Female				
#Skin:									
Basal Cell Adenoma, Basosquamous Tumor Benign, or Trichoepithelioma									
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)		1/50 (2%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	
.....									
#Skin:									
Basal Cell Carcinoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)		0/50 (0%)	
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Basal Cell Carcinoma or Basosquamous Tumor (malignant or NOS)									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)		0/50 (0%)	
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/150 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma									
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)		1/50 (2%)	
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 1.15%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	
.....									
#Skin:									
Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma									
		4/50 (8%)	1/50 (2%)	2/50 (4%)		0/50 (0%)		1/50 (2%)	
		6/50 (12%)				1/50 (2%)			
Overall Incidence	Total	13/200 (6.5%)	Mean 6.5%	SD 4.43%	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
Contract/Lab: All Laboratories
Species: RATS
Strain: F 344/N
Length of Study: CHRONIC

Toxicology Data Management System
Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: FEED

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Report Date: 03/20/2010

Male					Female				
#Skin:									
Fibroma									
		4/50 (8%)	1/50 (2%)	5/50 (10%)		0/50 (0%)	1/50 (2%)		
		3/50 (6%)				1/50 (2%)			
Overall Incidence	Total	13/200 (6.5%)	Mean 6.5%	SD 3.42%	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	
#Skin:									
Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma									
		4/50 (8%)	4/50 (8%)	5/50 (10%)		0/50 (0%)	3/50 (6%)		
		4/50 (8%)				1/50 (2%)			
Overall Incidence	Total	17/200 (8.5%)	Mean 8.5%	SD 1%	Total	4/150 (2.67%)	Mean 2.67%	SD 3.06%	
#Skin:									
Fibrosarcoma									
		0/50 (0%)	2/50 (4%)	0/50 (0%)		0/50 (0%)	0/50 (0%)		
		0/50 (0%)				1/50 (2%)			
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 2%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	
#Skin:									
Fibrosarcoma, Sarcoma, Myxosarcoma, or Fibrous Histiocytoma									
		0/50 (0%)	3/50 (6%)	0/50 (0%)		0/50 (0%)	2/50 (4%)		
		1/50 (2%)				1/50 (2%)			
Overall Incidence	Total	4/200 (2%)	Mean 2%	SD 2.83%	Total	3/150 (2%)	Mean 2%	SD 2%	
#Skin:									
Fibrous Histiocytoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)		
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Male						Female					
#Skin:											
Hemangioma											
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)			0/50	(0%)			0/50	(0%)
Overall Incidence	Total	0/200	(0%)	Mean 0%	SD 0%	Total	0/150	(0%)	Mean 0%	SD 0%	
#Skin:											
Hemangiosarcoma											
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)			0/50	(0%)			0/50	(0%)
Overall Incidence	Total	0/200	(0%)	Mean 0%	SD 0%	Total	0/150	(0%)	Mean 0%	SD 0%	
#Skin:											
Keratoacanthoma											
		3/50	(6%)	1/50	(2%)	2/50	(4%)	0/50	(0%)	0/50	(0%)
		4/50	(8%)					0/50	(0%)		
Overall Incidence	Total	10/200	(5%)	Mean 5%	SD 2.58%	Total	0/150	(0%)	Mean 0%	SD 0%	
#Skin:											
Lipoma											
		0/50	(0%)	1/50	(2%)	1/50	(2%)	0/50	(0%)	0/50	(0%)
		1/50	(2%)					0/50	(0%)		
Overall Incidence	Total	3/200	(1.5%)	Mean 1.5%	SD 1%	Total	0/150	(0%)	Mean 0%	SD 0%	
#Skin:											
Liposarcoma											
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)					0/50	(0%)		
Overall Incidence	Total	0/200	(0%)	Mean 0%	SD 0%	Total	0/150	(0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically
#: Denominator is number of animals necropsied

Version: Mar2010
Contract/Lab: All Laboratories
Species: RATS
Strain: F 344/N
Length of Study: CHRONIC

Toxicology Data Management System
Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: FEED

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Male						Female						
#Skin:												
Neural Crest Tumor												
		1/50	(2%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	1/50	(2%)
		0/50	(0%)						0/50	(0%)		
Overall Incidence	Total	1/200	(0.5%)	Mean	0.5%	SD	1%	Total	1/150	(0.67%)	Mean	0.67%
											SD	1.15%
#Skin:												
Neural Crest Tumor, Malignant												
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)
		1/50	(2%)						0/50	(0%)		
Overall Incidence	Total	1/200	(0.5%)	Mean	0.5%	SD	1%	Total	0/150	(0%)	Mean	0%
											SD	0%
#Skin:												
Neurofibroma or Schwannoma benign												
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)
		0/50	(0%)						0/50	(0%)		
Overall Incidence	Total	0/200	(0%)	Mean	0%	SD	0%	Total	0/150	(0%)	Mean	0%
											SD	0%
#Skin:												
Neurofibrosarcoma or Schwannoma (malignant or NOS)												
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)
		0/50	(0%)						0/50	(0%)		
Overall Incidence	Total	0/200	(0%)	Mean	0%	SD	0%	Total	0/150	(0%)	Mean	0%
											SD	0%
#Skin:												
Neurofibrosarcoma, Neurofibroma, or Schwannoma (benign, malignant or NOS)												
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)
		0/50	(0%)						0/50	(0%)		
Overall Incidence	Total	0/200	(0%)	Mean	0%	SD	0%	Total	0/150	(0%)	Mean	0%
											SD	0%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Vehicle: FEED

Report Date: 03/20/2010

		Male				Female			
#Skin: Sarcoma									
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	2/50 (4%)		
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 1.15%		Total	2/150 (1.33%)	Mean 1.33%	SD 2.31%
#Skin: Schwannoma Benign									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)		
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%		Total	0/150 (0%)	Mean 0%	SD 0%
#Skin: Schwannoma Malignant									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)		
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%		Total	0/150 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Carcinoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)		
		1/50 (2%)				1/50 (2%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%		Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
#Skin: Squamous Cell Carcinoma, Basal Cell Carcinoma, Basosquamous Tumor (malignant or NOS), or Carcinoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)		
		2/50 (4%)				1/50 (2%)			
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 2%		Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%

#: Denominator is number of animals necropsied

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: FEED

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Male					Female				
#Skin:									
Squamous Cell Papilloma									
		0/50 1/50	(0%) (2%)	0/50 (0%)	0/50 (0%)		0/50 0/50	(0%) (0%)	0/50 (0%)
Overall Incidence	Total	1/200	(0.5%)	Mean 0.5%	SD 1%	Total	0/150	(0%)	Mean 0% SD 0%
#Skin:									
Squamous Cell Papilloma or Papilloma									
		0/50 1/50	(0%) (2%)	0/50 (0%)	0/50 (0%)		0/50 0/50	(0%) (0%)	0/50 (0%)
Overall Incidence	Total	1/200	(0.5%)	Mean 0.5%	SD 1%	Total	0/150	(0%)	Mean 0% SD 0%
#Skin:									
Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma									
		3/50 6/50	(6%) (12%)	1/50 (2%)	2/50 (4%)		0/50 1/50	(0%) (2%)	0/50 (0%)
Overall Incidence	Total	12/200	(6%)	Mean 6%	SD 4.32%	Total	1/150	(0.67%)	Mean 0.67% SD 1.15%
#Skin:									
Squamous Cell Papilloma, Papilloma, or Keratoacanthoma									
		3/50 5/50	(6%) (10%)	1/50 (2%)	2/50 (4%)		0/50 0/50	(0%) (0%)	0/50 (0%)
Overall Incidence	Total	11/200	(5.5%)	Mean 5.5%	SD 3.42%	Total	0/150	(0%)	Mean 0% SD 0%
#Skin:									
Trichoepithelioma									
		0/50 0/50	(0%) (0%)	0/50 (0%)	0/50 (0%)		0/50 0/50	(0%) (0%)	1/50 (2%)
Overall Incidence	Total	0/200	(0%)	Mean 0%	SD 0%	Total	1/150	(0.67%)	Mean 0.67% SD 1.15%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010
Contract/Lab: All Laboratories
Species: RATS
Strain: F 344/N
Length of Study: CHRONIC

Toxicology Data Management System
Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: FEED

Male					Female				
#Skin: Sebaceous Gland: Adenoma									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)			0/50	(0%)		
Overall Incidence	Total	0/200	(0%)	Mean 0%	SD 0%	Total	0/150	(0%)	Mean 0% SD 0%
#Skin: Sebaceous Gland: Carcinoma or Adenoma									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)			0/50	(0%)		
Overall Incidence	Total	0/200	(0%)	Mean 0%	SD 0%	Total	0/150	(0%)	Mean 0% SD 0%
#Spinal Cord: Astrocytoma Benign									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)			0/50	(0%)		
Overall Incidence	Total	0/200	(0%)	Mean 0%	SD 0%	Total	0/150	(0%)	Mean 0% SD 0%
#Spinal Cord: Astrocytoma Malignant									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)			0/50	(0%)		
Overall Incidence	Total	0/200	(0%)	Mean 0%	SD 0%	Total	0/150	(0%)	Mean 0% SD 0%
#Spinal Cord: Glioma Malignant									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)			0/50	(0%)		
Overall Incidence	Total	0/200	(0%)	Mean 0%	SD 0%	Total	0/150	(0%)	Mean 0% SD 0%

*: Denominator is number of animals with tissues examined microscopically
#: Denominator is number of animals necropsied

Male							Female							
*Spleen: Fibrosarcoma														
		0/50	(0%)	0/49	(0%)	0/49	(0%)			0/50	(0%)	0/49	(0%)	
		0/50	(0%)							0/49	(0%)			
Overall Incidence	Total	0/198	(0%)	Mean	0%	SD	0%	Total	0/148	(0%)	Mean	0%	SD	0%
*Spleen: Fibrous Histiocytoma														
		0/50	(0%)	0/49	(0%)	1/49	(2%)			0/50	(0%)	0/49	(0%)	
		0/50	(0%)							0/49	(0%)			
Overall Incidence	Total	1/198	(0.51%)	Mean	0.51%	SD	1.02%	Total	0/148	(0%)	Mean	0%	SD	0%
*Spleen: Hemangiosarcoma														
		1/50	(2%)	0/49	(0%)	0/49	(0%)			0/50	(0%)	0/49	(0%)	
		0/50	(0%)							0/49	(0%)			
Overall Incidence	Total	1/198	(0.51%)	Mean	0.5%	SD	1%	Total	0/148	(0%)	Mean	0%	SD	0%
*Spleen: Leiomyosarcoma														
		1/50	(2%)	0/49	(0%)	0/49	(0%)			0/50	(0%)	0/49	(0%)	
		0/50	(0%)							0/49	(0%)			
Overall Incidence	Total	1/198	(0.51%)	Mean	0.5%	SD	1%	Total	0/148	(0%)	Mean	0%	SD	0%
*Spleen: Sarcoma														
		0/50	(0%)	0/49	(0%)	0/49	(0%)			0/50	(0%)	0/49	(0%)	
		0/50	(0%)							0/49	(0%)			
Overall Incidence	Total	0/198	(0%)	Mean	0%	SD	0%	Total	0/148	(0%)	Mean	0%	SD	0%

*: Denominator is number of animals with tissues examined microscopically
#: Denominator is number of animals necropsied

Version: Mar2010
 Contract/Lab: All Laboratories
 Species: RATS
 Strain: F 344/N
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: FEED

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Male										Female				
#Stomach, Forestomach: Leiomyosarcoma														
		0/50	(0%)	1/50	(2%)	0/50	(0%)		0/50	(0%)		0/50	(0%)	
		0/50	(0%)						0/50	(0%)				
Overall Incidence	Total	1/200	(0.5%)	Mean	0.5%	SD	1%	Total	0/150	(0%)	Mean	0%	SD	0%
#Stomach, Forestomach: Squamous Cell Carcinoma														
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)		0/50	(0%)	
		0/50	(0%)						0/50	(0%)				
Overall Incidence	Total	0/200	(0%)	Mean	0%	SD	0%	Total	0/150	(0%)	Mean	0%	SD	0%
#Stomach, Forestomach: Squamous Cell Carcinoma or Papilloma Squamous														
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)		1/50	(2%)	
		0/50	(0%)						0/50	(0%)				
Overall Incidence	Total	0/200	(0%)	Mean	0%	SD	0%	Total	1/150	(0.67%)	Mean	0.67%	SD	1.15%
#Stomach, Forestomach: Squamous Cell Papilloma														
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)		1/50	(2%)	
		0/50	(0%)						0/50	(0%)				
Overall Incidence	Total	0/200	(0%)	Mean	0%	SD	0%	Total	1/150	(0.67%)	Mean	0.67%	SD	1.15%
#Stomach, Glandular: Carcinoma														
		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)		0/50	(0%)	
		0/50	(0%)						0/50	(0%)				
Overall Incidence	Total	0/200	(0%)	Mean	0%	SD	0%	Total	0/150	(0%)	Mean	0%	SD	0%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: Mar2010

Contract/Lab: All Laboratories

Species: RATS

Strain: F 344/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL

Vehicle: FEED

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Report Date: 03/20/2010

Male										Female					
#Stomach, Glandular: Carcinoma or Adenoma															
		0/50	(0%)	0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)		
		0/50	(0%)							0/50	(0%)				
Overall Incidence	Total	0/200	(0%)	Mean	0%	SD	0%	Total		0/150	(0%)	Mean	0%	SD	0%

#Stomach, Glandular: Lipoma															
		0/50	(0%)	0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)		
		0/50	(0%)							0/50	(0%)				
Overall Incidence	Total	0/200	(0%)	Mean	0%	SD	0%	Total		0/150	(0%)	Mean	0%	SD	0%

#Stomach, Glandular: Sarcoma															
		0/50	(0%)	0/50	(0%)	0/50	(0%)			0/50	(0%)	0/50	(0%)		
		0/50	(0%)							0/50	(0%)				
Overall Incidence	Total	0/200	(0%)	Mean	0%	SD	0%	Total		0/150	(0%)	Mean	0%	SD	0%

*Testes: Adenoma															
		46/50	(92%)	49/50	(98%)	42/50	(84%)								
		46/50	(92%)												
Overall Incidence	Total	183/200	(91.5%)	Mean	91.5%	SD	5.74%								

*Testes: Hemangioma															
		0/50	(0%)	0/50	(0%)	0/50	(0%)								
		0/50	(0%)												
Overall Incidence	Total	0/200	(0%)	Mean	0%	SD	0%								

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

		Male						Female						
*Thymus:														
Thymoma Benign														
		0/48	(0%)	0/47	(0%)	1/48	(2%)	0/46	(0%)	0/49	(0%)			
		0/41	(0%)					0/50	(0%)					
Overall Incidence	Total	1/184	(0.54%)	Mean	0.52%	SD	1.04%	Total	0/145	(0%)	Mean	0%	SD	0%
*Thymus:														
Thymoma Malignant														
		0/48	(0%)	0/47	(0%)	0/48	(0%)	0/46	(0%)	0/49	(0%)			
		0/41	(0%)					0/50	(0%)					
Overall Incidence	Total	0/184	(0%)	Mean	0%	SD	0%	Total	0/145	(0%)	Mean	0%	SD	0%
*Thymus:														
Thymoma NOS														
		0/48	(0%)	0/47	(0%)	0/48	(0%)	0/46	(0%)	0/49	(0%)			
		0/41	(0%)					0/50	(0%)					
Overall Incidence	Total	0/184	(0%)	Mean	0%	SD	0%	Total	0/145	(0%)	Mean	0%	SD	0%
*Thymus:														
Thymoma: Benign, Malignant, NOS														
		0/48	(0%)	0/47	(0%)	1/48	(2%)	0/46	(0%)	0/49	(0%)			
		0/41	(0%)					0/50	(0%)					
Overall Incidence	Total	1/184	(0.54%)	Mean	0.52%	SD	1.04%	Total	0/145	(0%)	Mean	0%	SD	0%
*Thyroid Gland: C-Cell:														
Adenoma														
		5/50	(10%)	6/50	(12%)	7/50	(14%)	3/49	(6%)	4/50	(8%)			
		5/48	(10%)					2/47	(4%)					
Overall Incidence	Total	23/198	(11.62%)	Mean	11.6%	SD	1.81%	Total	9/146	(6.16%)	Mean	6.13%	SD	1.87%

*: Denominator is number of animals with tissues examined microscopically
#: Denominator is number of animals necropsied

Version: Mar2010

Contract/Lab: All Laboratories

Species: RATS

Strain: F 344/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL

Vehicle: FEED

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Report Date: 03/20/2010

		Male				Female			
*Thyroid Gland: C-Cell: Carcinoma									
		4/50 (8%) 1/48 (2%)	1/50 (2%)	1/50 (2%)		1/49 (2%) 0/47 (0%)		1/50 (2%)	
Overall Incidence	Total	7/198 (3.54%)	Mean 3.52%	SD 2.99%	Total	2/146 (1.37%)	Mean 1.35%	SD 1.17%	
*Thyroid Gland: C-Cell: Carcinoma or Adenoma									
		9/50 (18%) 6/48 (13%)	7/50 (14%)	8/50 (16%)		4/49 (8%) 2/47 (4%)		5/50 (10%)	
Overall Incidence	Total	30/198 (15.15%)	Mean 15.12%	SD 2.39%	Total	11/146 (7.53%)	Mean 7.47%	SD 2.93%	
*Thyroid Gland: Follicular Cell: Adenoma									
		2/50 (4%) 0/48 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/47 (0%)		0/50 (0%)	
Overall Incidence	Total	2/198 (1.01%)	Mean 1%	SD 2%	Total	0/146 (0%)	Mean 0%	SD 0%	
*Thyroid Gland: Follicular Cell: Carcinoma									
		0/50 (0%) 0/48 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 1/47 (2%)		0/50 (0%)	
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	1/146 (0.68%)	Mean 0.71%	SD 1.23%	
*Thyroid Gland: Follicular Cell: Carcinoma or Adenoma									
		2/50 (4%) 0/48 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 1/47 (2%)		0/50 (0%)	
Overall Incidence	Total	2/198 (1.01%)	Mean 1%	SD 2%	Total	1/146 (0.68%)	Mean 0.71%	SD 1.23%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

		Male				Female			
#Tissue NOS:									
Lipoma									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)			0/50	(0%)		
Overall Incidence	Total	0/200	(0%)	Mean	0%	SD	0%	Total	0/150 (0%)
								Mean	0%
								SD	0%
#Tissue NOS:									
Paraganglioma									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		1/50	(2%)			0/50	(0%)		
Overall Incidence	Total	1/200	(0.5%)	Mean	0.5%	SD	1%	Total	0/150 (0%)
								Mean	0%
								SD	0%
#Tongue:									
Squamous Cell Carcinoma									
		0/50	(0%)	0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)			0/50	(0%)		
Overall Incidence	Total	0/200	(0%)	Mean	0%	SD	0%	Total	0/150 (0%)
								Mean	0%
								SD	0%
#Tongue:									
Squamous Cell Carcinoma or Papilloma Squamous									
		1/50	(2%)	0/50	(0%)	1/50	(2%)	0/50	(0%)
		1/50	(2%)					1/50	(2%)
Overall Incidence	Total	3/200	(1.5%)	Mean	1.5%	SD	1%	Total	1/150 (0.67%)
								Mean	0.67%
								SD	1.15%
#Tongue:									
Squamous Cell Papilloma									
		1/50	(2%)	0/50	(0%)	1/50	(2%)	0/50	(0%)
		1/50	(2%)					1/50	(2%)
Overall Incidence	Total	3/200	(1.5%)	Mean	1.5%	SD	1%	Total	1/150 (0.67%)
								Mean	0.67%
								SD	1.15%

*: Denominator is number of animals with tissues examined microscopically
#: Denominator is number of animals necropsied

Version: Mar2010

Contract/Lab: All Laboratories

Species: RATS

Strain: F 344/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL

Vehicle: FEED

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Report Date: 03/20/2010

Male												Female			
#Tooth: Adamantinoma Malignant															
		0/50	(0%)	0/50	(0%)	0/50	(0%)			0/50	(0%)			0/50	(0%)
		0/50	(0%)							0/50	(0%)				
Overall Incidence	Total	0/200	(0%)	Mean	0%	SD	0%		Total	0/150	(0%)	Mean	0%	SD	0%
.....															
#Tooth: Odontoma															
		0/50	(0%)	0/50	(0%)	0/50	(0%)			0/50	(0%)			0/50	(0%)
		0/50	(0%)							0/50	(0%)				
Overall Incidence	Total	0/200	(0%)	Mean	0%	SD	0%		Total	0/150	(0%)	Mean	0%	SD	0%
.....															
*Urinary Bladder: Carcinoma or Papilloma															
		0/50	(0%)	1/49	(2%)	0/50	(0%)			0/50	(0%)			0/50	(0%)
		0/50	(0%)							0/50	(0%)				
Overall Incidence	Total	1/199	(0.5%)	Mean	0.51%	SD	1.02%		Total	0/150	(0%)	Mean	0%	SD	0%
.....															
*Urinary Bladder: Hemangiosarcoma															
		0/50	(0%)	0/49	(0%)	0/50	(0%)			0/50	(0%)			0/50	(0%)
		0/50	(0%)							0/50	(0%)				
Overall Incidence	Total	0/199	(0%)	Mean	0%	SD	0%		Total	0/150	(0%)	Mean	0%	SD	0%
.....															
*Urinary Bladder: Leiomyosarcoma															
		0/50	(0%)	0/49	(0%)	0/50	(0%)			0/50	(0%)			0/50	(0%)
		0/50	(0%)							0/50	(0%)				
Overall Incidence	Total	0/199	(0%)	Mean	0%	SD	0%		Total	0/150	(0%)	Mean	0%	SD	0%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Length of Study: CHRONIC

Vehicle: FEED

Report Date: 03/20/2010

Male								Female						
*Urinary Bladder: Papilloma														
		0/50	(0%)	1/49	(2%)	0/50	(0%)			0/50	(0%)			
		0/50	(0%)							0/50	(0%)			
Overall Incidence	Total	1/199	(0.5%)	Mean	0.51%	SD	1.02%	Total	0/150	(0%)	Mean	0%	SD	0%
.....														
#Uterus: Adenoma														
									0/50	(0%)		0/50	(0%)	
									1/50	(2%)				
Overall Incidence								Total	1/150	(0.67%)	Mean	0.67%	SD	1.15%
.....														
#Uterus: Carcinoma														
									0/50	(0%)		0/50	(0%)	
									0/50	(0%)				
Overall Incidence								Total	0/150	(0%)	Mean	0%	SD	0%
.....														
#Uterus: Deciduoma Benign														
									0/50	(0%)		0/50	(0%)	
									0/50	(0%)				
Overall Incidence								Total	0/150	(0%)	Mean	0%	SD	0%
.....														
#Uterus: Hemangioma														
									0/50	(0%)		0/50	(0%)	
									0/50	(0%)				
Overall Incidence								Total	0/150	(0%)	Mean	0%	SD	0%

#: Denominator is number of animals necropsied

Version: Mar2010
Contract/Lab: All Laboratories
Species: RATS
Strain: F 344/N
Length of Study: CHRONIC

Toxicology Data Management System
Tumor Incidence for Selected Control Animal Groups
Route: ORAL
Vehicle: FEED

Male			Female		
#Uterus:					
Hemangiosarcoma					
		0/50 (0%)		0/50 (0%)	
		0/50 (0%)			
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	
#Uterus:					
Leiomyosarcoma					
		0/50 (0%)		1/50 (2%)	
		0/50 (0%)			
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	
#Uterus:					
Polyp Stromal					
		10/50 (20%)		14/50 (28%)	
		10/50 (20%)			
Overall Incidence	Total	34/150 (22.67%)	Mean 22.67%	SD 4.62%	
#Uterus:					
Sarcoma					
		0/50 (0%)		0/50 (0%)	
		0/50 (0%)			
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	
#Uterus:					
Sarcoma Stromal					
		0/50 (0%)		0/50 (0%)	
		0/50 (0%)			
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	
*: Denominator is number of animals with tissues examined microscopically					
#: Denominator is number of animals necropsied					

Length of Study: CHRONIC

Vehicle: FEED

Report Date: 03/20/2010

Male					Female				
#Uterus: Sarcoma Stromal or Polyp Stromal									
					10/50 10/50	(20%) (20%)			14/50 (28%)
Overall Incidence					Total	34/150 (22.67%)	Mean	22.67%	SD 4.62%
.....									
#Uterus: Schwannoma Malignant									
					0/50 0/50	(0%) (0%)			0/50 (0%)
Overall Incidence					Total	0/150 (0%)	Mean	0%	SD 0%
.....									
#Vagina: Polyp									
					0/50 0/50	(0%) (0%)			0/50 (0%)
Overall Incidence					Total	0/150 (0%)	Mean	0%	SD 0%
.....									
#Vagina: Sarcoma									
					0/50 0/50	(0%) (0%)			0/50 (0%)
Overall Incidence					Total	0/150 (0%)	Mean	0%	SD 0%
.....									
#Zymbal's Gland: Adenoma									
		0/50 0/50	(0%) (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)			0/50 (0%)
Overall Incidence		Total	0/200 (0%)	Mean	0%	SD 0%	Total	0/150 (0%)	Mean 0% SD 0%

#: Denominator is number of animals necropsied

Version: Mar2010

Contract/Lab: All Laboratories

Species: RATS

Strain: F 344/N

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL

Vehicle: FEED

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Report Date: 03/20/2010

Male												Female						
#Zymbal's Gland: Carcinoma			0/50	(0%)		1/50	(2%)		0/50	(0%)			1/50	(2%)			0/50	(0%)
			0/50	(0%)									0/50	(0%)				
	Overall Incidence	Total	1/200	(0.5%)	Mean	0.5%	SD	1%	Total	1/150	(0.67%)	Mean	0.67%	SD	1.15%			
.....																		
#Zymbal's Gland: Carcinoma or Adenoma			0/50	(0%)		1/50	(2%)		0/50	(0%)			1/50	(2%)			0/50	(0%)
			0/50	(0%)									0/50	(0%)				
	Overall Incidence	Total	1/200	(0.5%)	Mean	0.5%	SD	1%	Total	1/150	(0.67%)	Mean	0.67%	SD	1.15%			

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied